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**TELEMETRIC FOLLOW-UP OF PHYSICAL ACTIVITY IN PATIENTS WITH HEART FAILURE TO  
EVALUATE DISEASE PROGRESSION**

PhD thesis booklet

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## Introduction

Diseases of civilization and endemic diseases are typical challenges of today's modern societies. Diseases of civilization are caused or aggravated by the lifestyle of modern man, while endemic diseases are morbidities with constant and significant prevalence in a given population. Manifestations of the two overlap (diabetes mellitus, obesity, depression, cancer, and cardiovascular diseases), as most diseases are diseases of civilization. These conditions affect large numbers of people in the population and place a great burden both on the person affected and the healthcare system. Naturally, achievements of civilization provided mankind with numerous useful tools and practical inventions, but so did result in a more sedentary lifestyle. In 1953, two papers that are now highly cited have been published in *Lancet* investigating the connection between physical activity and heart diseases. The authors were pioneers in describing that myocardial infarction is less common in men engaged in physically active work than among those in the same age group in sedentary jobs (Morris 1953).

National surveys also support the finding that Hungary is among developed countries with the highest rates of cardiovascular diseases. Our national health indicators, including life expectancy at birth and premature death rate caused by cardiovascular diseases by international standards are disappointingly poor. While in 2013, standardised mortality rate for ischemic heart disease in the EU member states was 132 per 100,000 persons, in Hungary this number exceeded 350<sup>1</sup>.

According to a report from 2017, in Europe alone 3.9 million people died of cardiovascular disease. More than 1.8 million of those were people from EU member states (EHN 2017 statistics).

Heart failure is a type of cardiovascular disease, with an increasing prevalence attributed to the aging societies of the developed world.

Based on the international guidelines of the treatment of chronic heart failure eliminating the symptoms, preventing/reducing the length of hospitalisation, and improving survival rates are major goals. Alleviating the existing symptoms, improving the quality of life, and supporting the functional capacity of patients are also important. Primary tools to treat heart failure are drug and instrumental therapies, the latter of which also allow for remote monitoring by advances in technology. Remote patient monitoring is an advanced,

telemedical technology to enable monitoring of patients outside of conventional clinical settings and optimisation of scheduling medical appointments.

In accordance with the notions above, the aim of our study was disease surveillance and monitoring physical activity of our patients, as to be able to overcome the limitations of making prognoses on the deterioration in their health states. In my thesis the most important epidemiological findings on heart failure and treatment possibilities are reviewed. Goals and results of our investigations are also outlined, in hope they could eventually be implemented in the routine clinical practice.

## **Aims**

1. To develop a method enabling better comparability of data (daily physical activity %) obtained by accelerometers in cardiac resynchronization therapy (CRT) devices.
2. To measure energy consumption (MET) of participants using telemetric and Actigraph GT3X+ data.
3. To develop a method to help estimate 6-minute walk test (6MWT) distance based on CRT telemetric data.
4. To develop a method to predict clinical deterioration based on telemetric data.

## **Materials and methods**

Our longitudinal non-randomised controlled study with simple random sampling was conducted on patients with systolic failure at the Heart Institute, University of Pécs Medical School (PTEKK), with implantable devices utilizing the so-called Biotronik Home Monitoring® (HM) system. PTEKK is a healthcare centre for the South Transdanubian Region, so all patients were from that part of Hungary. Originally, based on the criteria above, 21 patients were selected. 1 patient withdrew due to limited walking ability and 3 others did not want to participate in the study (N=17; age  $57.35 \pm 9.54$  years; body mass  $98.71 \pm 9.89$  kg; average BMI  $36.69 \pm 3.67$ ; 4 patients BMI  $\leq 30$ ; 13 patients BMI  $\geq 30$ ).

Selection criteria:

- According to the European Society of Cardiology (ESC) guidelines for heart failure:
  - systolic failure ejection fraction (EF)  $\leq 35$  %,

- left bundle branch block (QRS > 130 ms),
- New York Heart Association (NYHA) stages II-III,
- implanted Biotonik CRTP or CRTD device with HM system,
- continuous HM,
- age > 18 years, persistent sinus rhythm,
- signed informed consent (ESC 2016).

#### Exclusion criteria:

- NYHA stage IV,
- non-compliance to HM,
- limited walking ability resulting in the inability of completing the 6MWT,
- CRT patients with persistent atrial fibrillation,
- lack of cooperation.

## Methods

A relevant Research Ethics Approval Form (No. 6142) was issued by the Regional Committee for the Research Ethics at the Clinical Centre of the University of Pécs (see copy in Appendix I). A written informed consent form was signed by all participants (see copy in Appendix). The examination period was always 7 days, weekend included. Data measured in the examination period by implanted devices were downloaded from the HM system. Physical activity data of patients were also monitored and collected by an external Actigraph device. To determine MET values of activity categories, Freedson and colleagues set up an algorithm to correlate oxygen consumption data with beat per minute data.

Participants also filled in a questionnaire containing original questions and validated indexes. Original questions regarded sociodemographic characteristics i.e. frequency of physical activity, smoking, eating habits. Validated indexes included the 9-question Beck Depression Inventory (BDI), a Minnesota Living with Heart Failure Questionnaire (MLHFQ), and the 5-item version of World Health Organization General Well-Being Index (WHO WBI). Additional questions addressed details related to heart failure. After the questionnaire, participants completed the 6MWT. Detailed instructions on how to perform the 6MWT were given in advance. Patients were asked to walk as far as possible in six minutes, but they were allowed

to self-pace and rest as needed as they traverse back and forth along a marked, 20-metre long walkway. All participants had implanted devices with the HM system, containing built-in antennas enabling communication with a mobile phone.

### **Statistical tools**

Data analysis was carried out using SPSS 23 software package and Microsoft Excel. Means and standard deviations (SD) were calculated; statistical methods included descriptive statistics, chi-squared test, normality test, logistic regression analysis. For all variables,  $p$ -value < 0.05 indicated statistical significance.

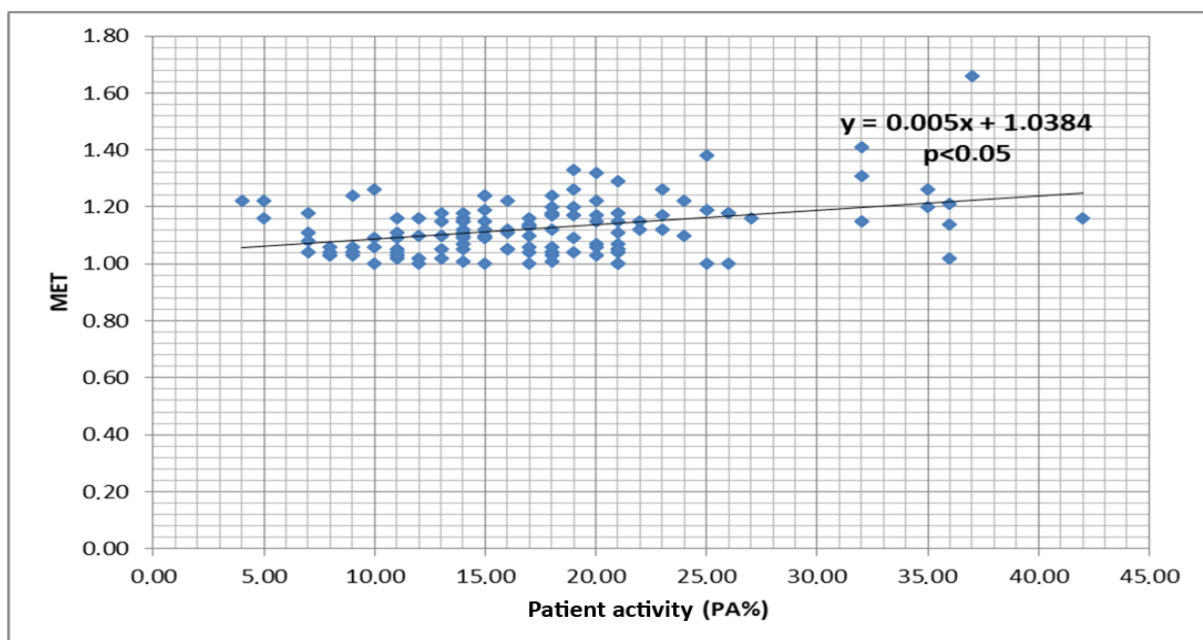
### **Results**

Patients were asked to complete a questionnaire containing original questions regarding sociodemographic characteristics i.e. physical activity, smoking, eating habits and questions to establish validated indexes i.e. the 9-question Beck Depression Inventory (BDI), a Minnesota Living with Heart Failure Questionnaire (MLHFQ), and the 5-item version of World Health Organization General Well-Being Index (WHO WBI). Additional questions addressed details related to heart failure.

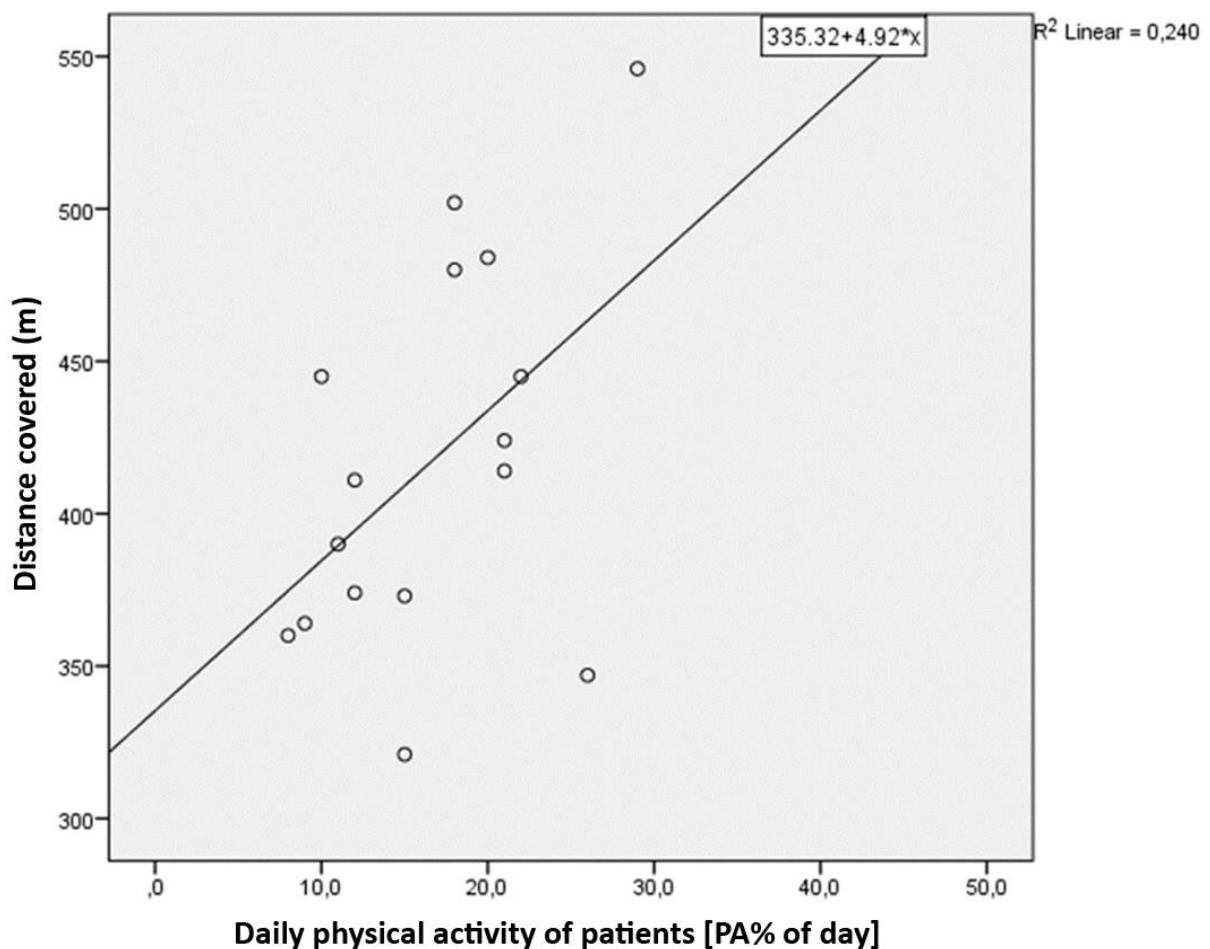
Based on questionnaire replies and 6MWT results the following correlations were observed. Patients before implantation experiencing shortness of breath (dyspnoea) on exertion achieved average or below the average results in 6MWT, while patients before implantation with no dyspnoea on exertion achieved above the average in 6MWT. The correlation was statistically significant ( $p=0.023$ ). After implantation, dyspnoea disappeared in 4, and subsided in 8 out of 17 patients ( $p<0.05$ ). From those who achieved average or above the average, 13 patients never or very rarely worried about their physical symptoms to the degree that they cannot think of anything else ( $p=0.015$ ), while from those who achieved average or below the average, 3 patients typically felt that way.

As for the validated indexes, BDI is a suitable measure of variations in mood. The test determines the severity of depression (minimal, mild, moderate, or severe). 1 patient did not answer the psychometric test, while 14 patients scored as having depression. MLHFQ replies, physical activity data obtained by Actigraph regarding i) sedentary time and ii) the amount of time the subject spends doing above moderate activity (Total Moderate to Vigorous Physical

Activity, Total MVPA) were also correlated with 6MWT results. Quality of life levels and 6MWT results showed statistically significant differences ( $p < 0.05$ ). A subsequent Scheffe post hoc test showed a statistically significant difference ( $p = 0.003$ ) between good and bad categories of life quality and the distance covered in 6MWT. Good, intermediate, and bad categories of life quality contained 6, 6, and 5 patients, respectively. After the statistical analysis in our group of patients, we found a correlation between BMI and sedentary time ( $p = 0.029$ ;  $R = 0.507$ ). Furthermore, patients with lower BMI spent more time doing intermediate activities ( $p = 0.021$ ;  $R = -0.555$ ). Patients who spent more time doing MVPA were able to cover a longer distance in 6MWT ( $p = 0.031$ ;  $R = 0.524$ ). Individual distances covered in 6MWT were measured manually. The average distance covered was  $416.58 \pm 48.2$  metres. Data collected by Actigraph can be divided into five categories reflecting activity intensity. The intensity of activity in our patients varied. Typically, our patients had a sedentary lifestyle, as shown by the MET values obtained. 86.79% of the examination period they spent sitting, which well reflects the low amount of physical exercise. Telemetric data obtained by the implanted devices (patient activity, PA%) average weekly activities were calculated. Individually, PA% greatly varied, but cannot serve information about activity intensity. To evaluate patient energy consumption based on PA%, we compared PA% values with MET data obtained by the Actigraph external sensor. Statistical calculations confirmed an intermediate correlation between PA% and MET ( $R = 0.37$ ;  $p = 0.00$ ). Our data also showed that for every unit change in PA%, the value of MET increases by 0.005.



Further analysing our data, 6MWT and PA% data were correlated using linear regression analysis, allowing the estimation of the distance covered in 6MWT based on PA% values. The following parameters were obtained:  $F = 4.409$ ;  $p = 0.05$ ;  $b_0$  parameter 335.321 ( $p = 0.00$ ), a  $b_1$  parameter 4.925 ( $p = 0.05$ ).



## Discussion

The incidence rate of systolic failure is dramatically increasing worldwide, including Hungary (Dickstein 2008; Roger 2010; Tomcsányi 2012). CRT is primarily effective in patients with left bundle branch block to improve clinical condition and cardiac performance (Dickstein 2008; McMurray 2013; EHRA/HRS 2012; Brignole 2013). Inherently, implanted accelerometers are suitable to monitor, evaluate, and characterise daily physical activity of patients. In order to quantify such qualitative data, we utilised the essential test method 6MWT and complemented it with the use of the Actigraph device, suitable to quantitatively measure physical activity. Using statistical methods, we characterised energy consumption of physical activity measured in our patients (Alosco 2012; Howell 2008). We also collected and analysed

data on the clinical condition of the participants by means of a questionnaire (Witham 2006). Taken together, next to early detection, therapy, and safe and economic follow-up of patients, the method we developed could broaden the use of the HM system (Varma 2010; Hindricks 2014).

In accordance with the literature, our patients had generally low levels of physical activity, which reduces their life expectancies (Witham 2006; Howell 2008; Melczer 2015). Based on these data, in favour of improving quality of life, developing a controllable training programme for the patients would be beneficial and inspiring to help them reach individually optimal physical capacity levels. Accelerometer data from implantable CRT devices (PA%) and Actigraph data (MET) show intermediate correlation ( $R=0.37$ ;  $p=0.00$ ). Our data also demonstrate that for every unit change in PA%, the value of MET increases by 0.005, allowing for prediction of patient oxygen consumption. Ricci and colleagues demonstrated that CRT devices detect life-threatening arrhythmias with an efficiency of at least 90% but have low efficiency (58.8%) in predicting adverse outcome (Ricci 2013). Based on our analysis we concluded that PA% data are useful in the prediction of distance covered in 6MWT, which may better predict clinical outcome.

## Results

- Our results show that patients with heart failure who exercise less than their already decreased exercise capacity have a shorter life expectancy.
- Our patients would require a personalised and controlled aerobic training programme, under the supervision of a specialist, a physiotherapist, and an exercise physiology expert.
- We developed a method that translates PA% data collected from CRT devices using the HM system into a clinically more useful MET value. Our method is suitable to predict oxygen consumption in patients.
- Distance covered in 6MWT is an important clinical parameter to estimate the aerobic capacity in patients. PA% in its present form obtained from CRT devices does not serve information in this regard. Our method allows for the prediction of the distance covered in 6MWT based on PA% data. Based on the equation, a line graph and a trendline display information easing clinical outcome assessment.



## **Future aims**

Our future aim is to substantiate our findings in a larger cohort and include patient follow-up, utilizing prediction of the distance covered in 6MWT in the daily routine, making it part of the monitoring process. It is also planned to use smart phone devices to complement our method.

## Acknowledgements

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## Publications

### List of publications related to the dissertation

#### "In extenso" publications

- Melczer Cs, Melczer L , Goják I , Kónyi A , Szabados S , Raposa LB , Oláh A , Ács P (2017) Reszinkronizációs készülékkel élő betegek fizikai aktivitásának összehasonlító vizsgálata telerias adatok alapján. ORVOSI HETILAP 158:(19) pp. 748-753.

**IF: 0,349**

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